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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,956	12/15/2005	Martin Hendrix	LeA 36 231	1061
35969	7590	04/02/2008	EXAMINER	
Bayer Health Care LLC 400 Morgan Lane West Haven, CT 06516			MOORE, SUSANNA	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			04/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,956

Applicant(s)

HENDRIX ET AL

Examiner

SUSANNA MOORE

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 6, 9-11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 2/21/2008 is acknowledged. Group I is the compounds of formula I. Applicant has not pointed to any errors in the Examiners analysis of the classification of the different inventions. Thus, the requirement is deemed proper and is therefore made **FINAL**.

In summary, there are eleven claims pending and seven under consideration. Claims 1-5 are compound claims. Claim 8 is a composition claim. Claims 6, 9-11 and 14 are methods of using and making claims, currently withdrawn from consideration. This is the first action on the merits. The application concerns some pyrazolo[3,4-d]pyrimidin-4-one compounds, compositions and uses thereof.

This application contains claims 6, 9-11 and 14, drawn to an invention nonelected with traverse in the paper of 2/21/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

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The following title is suggested: Substituted Pyrazolo[3,4-d]pyrimidin-4-one compounds as Phosphodiesterase Inhibitors.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 and 8 have "heterocyclic" used throughout the claims. However, the Specification, on page 7, gives definitions of some heterocycles but uses open-language, e.g. "preferred." What other ring systems does Applicant intend? Thus, said claims are indefinite.

Regarding claim 1, the variable R4 is not written in the alternative. Thus, said variable is vague.

Regarding claim 8, the term "medicament" is vague. Does Applicant intend composition?

Claims 1-5 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to solvates. But the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist.” The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyashita et. al. (Heterocycles, 1990, 31(7), 1309-14).

The instant invention claims compounds of formula (I), wherein X= oxygen, R⁴= pentan-3-yl, R² and R³= hydrogen and R¹= methyl or ethyl or phenyl.

The reference teaches compounds of formula (I), wherein X= oxygen, R⁴= methyl, R² and R³= hydrogen and R¹= methyl or ethyl or phenyl. See page 1310, compounds 2c, 2e, and 2f.

The difference between the reference and the instant Application is the substitution at the R⁴ variable, methyl versus Applicant's pentan-3-yl. Since a methyl group is considered a

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homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states "Compounds which are... homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Claims 1-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et. al. (CH 396924).

The instant invention claims compounds of formula (I), wherein X= oxygen or sulfur, R^4 = pentan-3-yl, R^2 and R^3 = hydrogen and R^1 = methyl or ethyl.

The reference teaches compounds of formula (I), wherein X= oxygen or sulfur, R^4 = isopropyl, R^2 = methyl, R^3 = hydrogen and R^1 = ethyl. See page 6, top left of page, and claims 1-8.

The difference between the reference and the instant Application is the substitution at the R^4 variable, isopropyl versus Applicant's pentan-3-yl. The same homolog used above applies here too.

Relevant references which have similar substituents at R^4 as those mentioned above:

CH 396923, Schmidt et. al., 01-1966;

CH 396927, Schmidt et. al., 01-1966;

GB 973361, Ciba; 10-1964;

DE 1156415, Schmidt et. al., 10-1963;

DE 1153023, Schmidt et. al., 08-1963;

DE 1149013, Schmidt et. al., 05-1963.

Double Patenting

No obviousness-type double patenting rejections over co-pending application 10525115 is being made because there is no incidental overlap when R¹ equals a phenyl. Thus, the obviousness-type double patenting was considered but not applied.

No obviousness-type double patenting rejections over co-pending application 10525119 is being made because the copending Application is drawn to method claims and a restriction between compounds and methods was done in the instant Application. Thus, the obviousness-type double patenting was considered but not applied.

No obviousness-type double patenting rejections over co-pending applications 10556437 and 10556224 are being made because there is no incidental overlap when R² equals a phenyl or heteroaryl. Thus, the obviousness-type double patenting was considered but not applied.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624